REMARKS

Claims 1-20 are pending in this application. Claims 21-28 previously have been canceled. The Applicants have amended independent Claims 1, 9, and 16 to recite that "the patient takes the medication prior to experiencing pain;" in other words, medication overuse disorder as used in the present claims involves the pre-emptive use of medication and is supported, *inter alia*, in the specification at page 8, lines 7-9. The present claims are not directed to treating headache; rather, they are directed to treating medication overuse disorder whereby medication is taken prior to experiencing pain.

Rejection Under 35 USC 102

Claims 1-20 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over Claims 1-17 of copending U.S. Appln. No. 11/039,506. The Applicants will address the merits of this provisional rejection when it ripens.

Claims 1-3, 10-17, 19-20, and 29 stand rejected under 35 USC 102(a) as anticipated by Schim (*Current Medical Research and Opinion*, Vol. 20, No.1, pp. 49-53, 2004). The Applicants respectfully disagree. However, in order to expedite prosecution only, the Applicants have amended all independent Claims 1, 9, and 16 to recite that "the patient takes the medication prior to experiencing pain." In other words, the present claims are directed to the preemptive use of medication not necessarily associated with an actual pain or ache. Schim does disclose or render obvious the present claims. While Schim discusses how "reducing the frequency and/or severity of migraine attacks could decrease the need for acute headache medication,"[1] Schim does not address the needs of patients that take medication in anticipation of, rather than in response to, a headache.

In summarizing one study, Schim states that "reduction in medication use was associated with a significantly lower frequency of migraine attacks per month, a reduced

[1] Schim, p. 49.

maximum severity of migraines, and a reduced incidence of migraine-associated vomiting."[2] Further, referring various studies of sufferers of chronic tension type headache (CTTH), Schim states those studies "found no significant difference in analgesic use between patients with CTTH treated with" Botulinum toxin type A and that "the average intake of analgesics by patients with CTTH over the first month after" Botulinum toxin type A injection "did not differ from that at baseline."[3] Nowhere does Shcim describe the ability of Botulinum toxin to assist those patients that take medication before they experience pains or aches. Indeed, it may be said that Schim leads the skilled artisan away from using Botulinum toxin to treat medication overuse, especially for certain types of headache. Since Schim does not describe each and every element of the present claims and does not lead a skilled artisan to the present claims, the Applicants respectfully request withdrawal of this rejection.

Claims 1-20 and 29 stand rejected under 35 USC 102(b) as anticipated by Tepper (*Cephalalgia*, Vol. 23, pp. 581-762, 2003). The Applicants respectfully disagree. Claims 1, 9, and 16 now recite that "the patient takes the medication prior to experiencing pain." As discussed above, the preemptive use of medication is not associated with an actual pain or ache. Tepper does not even hint at the efficacy of Botulinum toxin for treating the pre-emptive use of pain medication. A skilled artisan in view of Tepper actually may be lead to believe that medication overuse leads to reductions in headache frequency since Tepper's figure shows there is a lower occurrence of headache in medication "overusers" than "non-overusers" at baseline. The present claims, however, are directed to treating the taking of medication before pain is experienced. Since Tepper does not describe each and every element of the present claims and does not lead a skilled artisan to the present claims, the Applicants respectfully request withdrawal of this rejection.

Claims 1-20 and 29 stand rejected under 35 USC 102(b) as anticipated by Mathew (*Headache*, Vol. 42, p. 454; Abstract S107). The Applicants respectfully

[2] Schim, p. 51.
[3] Schim, p. 51.

disagree. As discussed, the Applicants have amended all independent Claims 1, 9, and 16 to recite that "the patient takes the medication prior to experiencing pain" so the claims are directed to the preemptive use of medication not necessarily associated with an actual pain or ache. Like Schim and Tepper, Mathew does disclose or render obvious the present claims. Rather, Mathew discusses Botulinum toxin type A as "an emerging treatment modality in headache disorders." Mathew states that all "patients had poor headache control, poor quality of life . . . and high acute medication intake in spite of detoxification from analgesics and appropriate prophylactic therapy." Mathew concludes that "Botulinum toxin type A in selected patients with chronic migraine appears to modify the disorder, reducing the disability and acute medication use." Ordinary acute medication use is not the same as the pre-emptive use of medication before pain is experienced, in accordance with the present claims. In fact, Mathew never mentions pre-emptive use of medication. Since Mathew does not describe each and every element of the present claims and does not lead a skilled artisan to the present claims, the Applicants respectfully request withdrawal of this rejection.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

Dated: 21 April 2008

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